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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HAWAII LABORERS PENSION FUND, Derivatively on Behalf of JOHNSON & JOHNSON, Plaintiff, vs. WILLIAM C. WELDON, MARY S. COLEMAN, JAMES G. CULLEN, MICHAEL M.E. JOHNS, ARNOLD G. LANGBO, SUSAN L. LINDQUIST, LEO F. MULLIN, WILLIAM D. PEREZ, CHARLES PRINCE, DAVID SATCHER, HENRY B. SCHACHT, RALPH S. LARSEN, ROBERT J. DARRETTA and JAMES T. LENEHAN, Defendants, – and – JOHNSON & JOHNSON, a New Jersey corporation, Nominal Defendant.	No. VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT FOR VIOLATIONS OF THE SECURITIES EXCHANGE ACT OF 1934, BREACH OF FIDUCIARY DUTY, ABUSE OF CONTROL, WASTE OF CORPORATE ASSETS AND UNJUST ENRICHMENT DEMAND FOR JURY TRIAL

Plaintiff, Hawaii Laborers Pension Fund, whose principal business address is 1440 Kapiolani Boulevard, Suite 800, Honolulu, Hawaii 96814, by its attorneys, submits this Verified Shareholder Derivative Complaint ("Complaint") against the defendants named herein.

SUMMARY OF THE ACTION

1. This action arises out of defendants' unlawful off-label marketing of drugs in a manner not approved by the FDA and which are harmful to elderly nursing-home patients suffering from dementia. During the period complained of herein, Johnson & Johnson ("J&J" or the "Company") and Omnicare, Inc. ("Omnicare") entered into a series of agreements whereby J&J would pay Omnicare kickbacks to undertake initiatives to increase prescriptions written for J&J's drugs in situations where the drugs were neither medically necessary nor safe. Omnicare provides pharmaceutical services and distributes pharmaceuticals primarily in long-term care facilities and nursing homes. This scheme violated federal and state laws and defrauded the U.S. government and every state participating in the Medicaid program, which only reimburses for medically efficacious drugs. This scheme also violated federal anti-kickback statutes, the Medicaid Rebate Act, fair trade practices and consumer protection laws. Under Medicaid's best price rule, after rebates for a drug reach a certain level for one customer, the supplier must also lower the price Medicaid pays. By disguising these rebates as other forms of payment to Omnicare, J&J avoided giving Medicaid similar rebates.

2. Omnicare and J&J's agreement also called for Omnicare to try to convince health care providers to switch drugs to those made by J&J, regardless of which drug was actually most beneficial for a particular patient. Switching prescriptions when one is already working is inherently risky. Doing it simply to increase profits is reckless and inexcusable.

3. Worse, however, is that as a result of this scheme, unneeded drugs were pushed on the elderly. Under a program nicknamed "one extra scrip per patient," patients were likely given drugs they did not need and in medical circumstances under which the FDA had specifically admonished J&J not to provide such drugs. Indeed, according to the U.S. government, one nursing-home patient who was a victim of the illegal kickback and rebate scheme received 67 different drugs.

4. Thus, the elderly were overcharged for their medication, received unneeded medication, and were illegally switched to J&J drugs for no medical reason. One of the drugs pushed on the elderly was Risperdal®, an atypical antipsychotic medication. In 1999, the FDA told J&J in writing that it was illegally marketing the drug for use on the elderly. Ultimately, after the FDA learned that its 1999 warning went unheeded and Risperdal® was being marketed for the off-label use it had specifically warned against, the FDA issued a harsher warning that elderly patients with dementia treated with Risperdal® were at an increased risk of death. In 2005, the FDA required Risperdal® to carry a "black box" warning label forbidding its use on elderly patients with dementia, one of J&J's favorite target demographics.

5. The focus was on maximizing short-term profits, not about patient safety or the long-term impact this scheme would have on J&J. The illegal marketing of Risperdal® worked. Between 1994 and 2008, Risperdal® sales alone were approximately $29 billion, with over 60% being attributed to off-label marketing. With Omnicare alone, the illegal kickback scheme allowed Omnicare's annual purchases of Risperdal® to grow from $100 million in 1999 to over $300 million in 2004. The scheme was widespread, prevalent and long lasting.

6. Even after the kickbacks and rebates stopped, the cover-up continued. In proxy statements J&J's Board of Directors solicited in favor of their elections, the Board failed to inform shareholders of the wrongdoing, its role in the wrongdoing, or the extent of the liabilities that the Company faces.

7. It was only a matter of time until investigative authorities learned of a scheme of this magnitude. It started with two "whistleblowers" from Omnicare filing *qui tam* actions. The U.S. Department of Justice (the "DOJ") soon intervened in these actions. Omnicare settled the claims against it for engaging in the kickback scheme for nearly $100 million. J&J did not.

8. On January 15, 2010, the DOJ filed a complaint against J&J and two of its subsidiaries, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (the successor in interest to Janssen Pharmaceutica Products, L.P. ("Janssen") and Ortho-McNeil Pharmaceutical Products, L.P.) and Johnson & Johnson Health Care Systems, Inc. The complaint revealed the scope and extent of J&J's violations of applicable law.

The DOJ's complaint accuses the Company of violating federal false claims and anti-kickback laws among others. The DOJ is seeking treble damages and restitution of J&J's unjust enrichment. In addition, a consumer class action was filed on behalf of nursing home patients harmed by J&J's and Omnicare's conduct. The Company faces significant liability from the DOJ and the consumer actions. In addition, J&J faces liability from litigation commenced by numerous states, including Arkansas, Louisiana, Pennsylvania, South Carolina and Texas, to recoup losses suffered as a result of violations of the Medicaid Act and various state consumer protection statutes.

9. J&J subsidiary Ortho-McNeil Pharmaceutical, LLC agreed in late April 2010 to plead guilty to a misdemeanor crime and pay a $6.14 million fine for misbranding its drugs. Another subsidiary, Ortho-McNeil-Janssen Pharmaceuticals, Inc. also agreed in April 2010 to pay $75 million to resolve claims for its illegal promotion of its drugs, specifically Topamax. It will also enter into a wide-ranging "corporate integrity agreement" with the office of Inspector General of the Department of Health & Human Services. The agreement requires Ortho-McNeil-Janssen Pharmaceuticals, Inc. to increase transparency and accountability. Thus, J&J has expended, and will continue to expend, significant sums of money reacting to illegal conduct. These actions have irreparably damaged J&J's corporate image and goodwill.

10. Plaintiff now brings this litigation on behalf of J&J and seeks to recompense J&J for the harm caused to it by the conduct of the individuals

responsible for the corporation's conduct – the directors and senior management – and to impose appropriate responsibility upon those individuals.

JURISDICTION AND VENUE

11. This Court has jurisdiction over all claims asserted herein pursuant to 28 U.S.C. §1332(a)(1) in that plaintiff and defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

12. This Court also has jurisdiction over this action pursuant to 28 U.S.C. §1331, because this action asserts a claims under §§14(a) and 29(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§78n(a) and 78cc(b), and has supplemental jurisdiction over the non-federal claims asserted herein under 28 U.S.C. §1367(a).

13. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

14. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this district, or is an individual who has sufficient minimum contacts with this judicial district so as to render the exercise of jurisdiction by the district courts of this district permissible under traditional notions of fair play and substantial justice.

15. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) because: (i) J&J maintains its principal place of business in this District; (ii) one or more of the

defendants either resides in or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to J&J, occurred in this District; and (iv) defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

THE PARTIES

16. Plaintiff Hawaii Laborers Pension Fund ("Hawaii Laborers") is, and at all times relevant hereto was, a shareholder of J&J. Hawaii Laborers is a citizen of the state of Hawaii.

17. Defendant William C. Weldon ("Weldon") has been J&J's Chairman and Chief Executive Officer ("CEO") since April 2002. He was elected to the Board and named Vice Chairman of the Board in 2001. Weldon has also been a member of J&J's Executive Committee since 1998. He is Chairman of the Finance Committee and has been since 2008. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 2000-2009. Weldon joined J&J in 1971 and served in several sales, marketing, and international management positions before becoming President of Ethicon Endo-Surgery in 1992, Company Group Chairman of Ethicon Endo-

Surgery in 1995, and Worldwide Chairman, Pharmaceuticals Group, in 1998. Weldon is a citizen of Pennsylvania.

18. Defendant Mary S. Coleman ("Coleman") is a J&J director and has been since September 2003. Coleman has been a member of J&J's Audit Committee and its Science & Technology Advisory Committee since 2003. She signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 2003-2009. Coleman is a citizen of Michigan.

19. Defendant James G. Cullen ("Cullen") is a J&J director and has been since 1995. Cullen is the Presiding Director of the Board. Cullen has been a member of the Audit Committee since 1998 and has been Chairman of that Committee since 2000. He is designated as an "audit committee financial expert" for purposes of §407 of the Sarbanes-Oxley Act of 2002. He has also been a member of the Nominating and Corporate Governance Committee since 2003. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 1999-2009. Cullen is a citizen of New Jersey.

20. Defendant Michael M.E. Johns ("Johns") is a J&J director and has been since March 2005. He has been a member of both the Compensation & Benefits Committee and the Science & Technology Advisory Committee since 2005. He signed the Company's Form 10-K disclosures, which describe the numerous federal

and state law enforcement and regulatory investigations of J&J, for the years 2005-2009. Johns is a citizen of Georgia.

21. Defendant Arnold G. Langbo ("Langbo") was a J&J director from 1991 until April 2010. Langbo was a member of the Nominating & Corporate Governance Committee from 2003 until 2010. He was Chairman of the Compensation & Benefits Committee from at least 1998 until 2010. Langbo was a member of the Audit Committee from at least 1998 to 2003. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 1999-2009. Defendant Langbo is a citizen of Florida.

22. Defendant Susan L. Lindquist ("Lindquist") is a J&J director and has been since 2004. Lindquist has been a member of J&J's Public Policy Advisory Committee since 2004. She signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 2004-2009. Lindquist is a citizen of Massachusetts.

23. Defendant Leo F. Mullin ("Mullin") is a J&J director and has been since July 1999. Mullin is also a member of J&J's Audit Committee and has been since 2000. He has been Chairman of the Public Policy Advisory Committee since 2005. Mullin was a member of J&J's Nominating & Corporate Governance Committee from 2000 to 2005. He signed the Company's Form 10-K disclosures, which describe the

numerous federal and state law enforcement and regulatory investigations of J&J, for the years 1999-2009. Mullin is a citizen of Georgia.

24. Defendant William D. Perez ("Perez") is a J&J director and has been since 2007. Perez is a member of both the Compensation & Benefits Committee and Public Policy Advisory Committee and has been since 2007. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 2007-2009. Perez is a citizen of Wisconsin.

25. Defendant Charles Prince ("Prince") is a J&J director and has been since 2006. Prince is Chairman of the Nominating & Corporate Governance Committee and is a member of the Compensation & Benefits Committee. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 2006-2009. Prince is a citizen of New York.

26. Defendant David Satcher ("Satcher") is a J&J director and has been since April 2002. Satcher is Chairman of the Science & Technology Advisory Committee. He is also a member of the Public Policy Advisory Committee and has been since 2002. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 2002-2009. Satcher is a citizen of Georgia.

27. Defendant Henry B. Schacht ("Schacht") was a J&J director from 1997 to April 2005. Schacht was a member of the Audit Committee from at least 1998 to 2005 and Chairman of the Nominating & Corporate Governance Committee from 1999 to 2005. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 1999-2004. Schacht is a citizen of New York.

28. Defendant Ralph S. Larsen ("Larsen") was J&J's CEO from 1989 to April 2002. Larsen was also a J&J director from 1987 to April 2002. Larsen joined J&J in 1962 and held numerous positions with the Company before being appointed Company Group Chairman in 1986. Upon departing J&J in 2002, Larsen agreed to provide services requested by the new CEO for a period of up to five years. Larsen is a citizen of Florida.

29. Defendant Robert J. Darretta ("Darretta") was J&J's Vice Chairman of the Board from January 2004 to February 2007 and a director from January 2002 to February 2007. Darretta was also J&J's Executive Vice President, Finance and Chief Financial Officer ("CFO") from 2002 to December 2006 and Vice President, Finance and CFO from 1997 to 2002. He signed the Company's Form 10-K disclosures, which describe the numerous federal and state law enforcement and regulatory investigations of J&J, for the years 2001-2006. Darretta joined J&J in 1968. Darretta is a citizen of New Jersey.

30. Defendant James T. Lenehan ("Lenehan") was J&J's Vice Chairman of the Board from February 2001 to February 2004. Lenehan was also J&J's President from 2002 to 2004. Lenehan joined J&J in 1976 and held several marketing management positions; became a Company Group Chairman in 1993; was named Worldwide Chairman, Consumer Pharmaceuticals & Professional Group in 1994; and was named Worldwide Chairman, Medical Devices & Diagnostics Group in 1999. Lenehan was also a member of J&J's Executive Committee from at least 1998 to 2003. Defendant Lenehan is a citizen of Pennsylvania.

31. Nominal defendant J&J is a corporation organized under the laws of New Jersey with its principal offices and headquarters located in New Brunswick, New Jersey.

32. The defendants identified in ¶¶17-30 herein are referred to the "Individual Defendants." The defendants identified in ¶¶17-20 and 22-26 are referred to as the "Current Director Defendants," and the defendants identified in ¶¶27-30 are referred to as the "Former Director Defendants."

DUTIES OF THE J&J DIRECTORS AND OFFICERS

33. Each director and officer of J&J owed J&J and its public shareholders the duty to exercise the highest degree of loyalty, good faith, independence and candor in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. As the Delaware Chancery Court explained: "Loyalty. Good faith. Independence. Candor. These are words pregnant

with obligation. The Supreme Court did not adorn them with half-hearted adjectives. Directors should not take a seat at the board table prepared to offer only conditional loyalty, tolerable good faith, reasonable disinterest or formalistic candor." *In re Tyson Foods, Inc. Consol. S'holder Litig.*, No. 1106-CC, 2007 Del. Ch. LEXIS 120, at *10-*11 (Del. Ch. Aug. 15, 2007).

34. The conduct of J&J's directors and officers complained of herein involves a knowing and culpable violation of their fiduciary obligations, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders which the directors and officers were aware, or should have been aware, posed a risk of serious injury to the Company. The illegal conduct of J&J's directors and officers has been ratified by J&J's Board, which has failed to take any action against them, despite knowledge of such actions and demands that proper remedial and preventative action be taken.

35. To discharge their fiduciary duties of loyalty, good faith, independence and candor, J&J's directors and officers were required, among other things, to:

(a) in good faith, manage, conduct, supervise and direct the business and affairs of J&J and its subsidiaries in accordance with the applicable laws, and the charter and by-laws of J&J;

(b) neither violate nor knowingly permit any director, officer or employee of J&J and its subsidiaries to violate applicable federal or state laws, rules and regulations or any rule or regulation of J&J;

(c) remain informed as to the status of J&J's operations, and upon receipt of notice or information of imprudent, unsound or unlawful practices, to make a reasonable inquiry in connection therewith, and to take steps to correct such conditions or stop such practices; and

(d) ensure that J&J was operated in a diligent, honest and prudent manner in compliance with all applicable federal and state laws, rules and regulations.

36. By reason of their corporate positions and their ability to control the business and corporate affairs of J&J, defendants were required to use their ability to control J&J in a fair, just and equitable manner, as well as to act in furtherance of the best interests of J&J and its stockholders and not in furtherance of their own personal interests or ideology. In violation of their fiduciary duties, defendants caused J&J to conduct its business in an unsafe, imprudent, dangerous and illegal manner.

37. Defendants participated in the wrongdoing complained of herein in order to improperly benefit themselves by pursuing their own personal ideological agendas instead of what was in the best interests of the Company, and to remain as directors and officers of a public corporation and to continue and prolong the illusion of J&J's success and to conceal the adverse facts concerning J&J's dismal record of compliance with federal and state health care laws and regulations so that they could protect and perpetuate their directorial and/or executive positions and increase the substantial compensation, perks and prestige they obtained thereby. Such participation involved, among other things, planning and creating (or causing to be

planned and created), proposing (or causing the proposal of) and authorizing, approving and acquiescing in the illegal conduct complained of herein.

38. Defendants breached their duties of loyalty and good faith by allowing or by themselves causing the violations of the Medicaid Act, the Medicaid Rebate Act, the federal anti-kick back statutes, fair trade practices and consumer protection laws, and the misrepresentation of financial results and prospects, as detailed herein. Each defendant participated in the issuance and/or review of false and/or misleading statements, including the preparation of false and/or misleading press releases, SEC filings and/or reports to J&J shareholders. In addition, as a result of defendants' illegal action and course of conduct, the Company is now the subject of regulatory actions and private lawsuits that allege violations of federal laws.

39. **Board Committees**. The Board of Directors has a standing Audit Committee, Compensation & Benefits Committee and Nominating & Corporate Governance Committee, each comprised entirely of non-employee directors determined to be "independent" under the listing standards of the NYSE. Under their written charters adopted by the Board, each of these committees is authorized and assured of appropriate funding to retain and consult with external advisors, consultants and counsel. In addition, the Board has a standing Public Policy Advisory Committee, Science & Technology Advisory Committee, and Finance Committee, each comprised of independent directors and members of management.

40. The **Audit Committee** is responsible for providing oversight of financial management and the independent auditors and ensuring: (1) that management is maintaining an adequate system of internal control such that there is reasonable assurance that assets are safeguarded and that financial reports are properly prepared; (2) that there is consistent application of generally accepted accounting principles; and (3) that there is compliance with management's policies and procedures. In addition, the Audit Committee is responsible for assisting the Board in its oversight of legal compliance programs. In performing these functions, the Audit Committee meets with the independent auditors, management, and internal auditors (including in private sessions) to review their work and confirm that they are properly discharging their respective responsibilities. In addition, the Audit Committee recommends the independent auditors for appointment by the Board of Directors.

41. According to the Charter of the Audit Committee that has been in place since at least 2001, Audit Committee members were responsible for assisting the Board in oversight of the Company's compliance with legal and ethical issues. The Audit Committee, comprised currently and formerly of defendants Coleman, Cullen, Langbo, Mullin and Schacht, according to the Charter, was required to review and monitor the results of compliance programs. The Audit Committee met three times in both 1999 and 2000, four times in 2001, and five times each year from 2002 to 2004.

42. The **Compensation & Benefits Committee** is responsible for discharging the Board's duties and responsibilities relating to compensation of the

Company's non-employee directors and executive officers and overseeing the management of the various pension, long-term incentive, savings, and health and welfare plans that cover the Company's employees. This committee met six times in 2009.

43. The Compensation & Benefits Committee's duties and responsibilities under its charter with respect to the compensation of the Company's directors and executive officers include:

- setting the Chairman/CEO's compensation level based on the independent directors' annual evaluation of his or her performance;
- reviewing and providing oversight of the development of the Company's compensation philosophy and composition of the group of peer companies used for comparison of executive compensation;
- approving the establishment of competitive targets versus the group of peer companies used for comparison of executive compensation and all equity-based plans requiring shareholder approval;
- reviewing the eligibility criteria and award guidelines for the compensation programs in which the executive officers participate;
- reviewing and approving management-recommended compensation actions for the Company's executive officers, including setting base salaries, annual incentive bonuses, long-term incentive awards, severance benefits and perquisites; and
- reviewing and approving compensation for the non-employee directors.

44. The Compensation & Benefits Committee also reviews the compensation philosophy and policies of the Management Compensation Committee (the "MCC"), a non-Board committee comprised of defendant Weldon and two members of management that determines management compensation and establishes perquisites

and other compensation policies for employees (except for executive officers of the Company). The Compensation & Benefits Committee is also responsible for the administration of the Company's performance bonus and long-term incentive plans and is the approving authority for management recommendations with respect to performance bonuses and long-term incentive awards under those plans.

45. The **Nominating & Corporate Governance Committee** is responsible for overseeing matters of corporate governance, including the evaluation of the performance and practices of the Board of Directors.

46. The committee also oversees the process for performance evaluations of the committees of the Board. It is also within the charter of the Nominating & Corporate Governance Committee to review the Company's executive succession plans and executive resources. In addition, the Nominating & Corporate Governance Committee reviews possible candidates for the Board and recommends the nominees for directors to the Board for approval. This committee met four times in 2009.

47. According to its Charter, which has been in place since at least 2003, the Nominating & Corporate Governance Committee is responsible for assisting the Board in its oversight of the corporate governance affairs of the Company. In furtherance of these duties, the Nominating & Corporate Governance Committee's Charter requires its members to annually review the corporate governance practices and policies of the Company. The Nominating & Corporate Governance Committee

met three times in both 1999 and 2000, four times in both 2001 and 2002, seven times in 2003, and five times in 2004.

48. The **Public Policy Advisory Committee** is comprised of independent directors and the Company's General Counsel and Vice Presidents for Corporate Affairs, Worldwide Operations, and Government Affairs and Policy. The Public Policy Advisory Committee reviews the Company's policies, programs and practices on public health issues regarding the environment and the health and safety of employees. The Public Policy Advisory Committee also reviews the Company's governmental affairs and policies and other public policy issues facing the Company. The Public Policy Advisory Committee advises and makes recommendations to the Board on these issues as appropriate. This committee met three times in 2009.

49. The **Science & Technology Advisory Committee** is comprised of independent directors and the Company's Vice President, Science and Technology. It advises the Board on scientific matters, including major internal projects, interaction with academic and other outside research organizations, and the acquisition of technologies and products. This committee met four times in 2009.

50. The **Finance Committee** is comprised of the Chairman and Presiding Director of the Board. The Finance Committee exercises the management authority of the Board during the intervals between Board meetings. The Finance Committee generally does not hold formal meetings and instead acts from time-to-time between Board meetings by unanimous written consent in lieu of a meeting, as needed. Any

such action is taken pursuant to specific advance delegation by the Board or is later ratified by the Board.

51. Each of the Audit, Compensation & Benefits and Nominating & Corporate Governance Committees met at least twice during 2009 in Executive Sessions without members of management present. The independent directors met seven times during 2009 in Executive Sessions, without the Chairman/CEO or any other member of management present, at which the Presiding Director acted as Chairman.

52. **Board Oversight of Risk Management**. The Board has assumed responsibility for risk management, given that the Company faces risk in many different areas, including business strategy, government regulation, financial condition, health care compliance, reputation, intellectual property, and trade secrets.

53. The Board meets at least annually with key members of management with primary responsibility for management of risk in their respective areas of responsibility, including the Company's Chairman/CEO; CFO; Controller; Treasurer; Vice President, Human Resources and General Counsel; Corporate Secretary; Chief Compliance Officer; Vice Presidents of Corporate Affairs, Government Affairs & Policy, Worldwide Operations, Science & Technology, and Corporate Internal Audit; and the Worldwide Chairman and Chief Compliance Officer of each of the Company's business segments. The Board also receives regular reports on aspects of the Company's risk management from senior representatives of the Company's

independent auditors. In addition, the Audit Committee (the current Chairman of which is also the independent Presiding Director) meets in private sessions with each of the CFO, Vice President, Human Resources and General Counsel, Chief Compliance Officer, Vice President of Corporate Internal Audit, and representatives of the Company's independent auditors at the conclusion of every regularly scheduled meeting, where aspects of risk management are discussed.

54. Such meetings served (or should have served) to put the Board on notice as to both the illegal kickback schemes and off-label drug marketing.

APPLICABLE LAWS AND REGULATIONS IMPLICATED BY DEFENDANTS' CONDUCT

55. J&J operates in a highly regulated industry. The Federal Health Care Program Anti-Kickback Statute, enacted as §1128B(b) of the Social Security Act, 42 U.S.C. §1320a-7b, prohibits persons from paying, soliciting or receiving illegal remunerations in order to induce business reimbursable under federal or state health care programs (here, Medicaid). 42 U.S.C. §1320a-7b(a). The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. 42 U.S.C. §1320a-7b(b). The prohibited conduct includes remuneration intended to induce referrals of patients or the purchasing, leasing or ordering, or arranging of any good, facility, service or item to be paid for the federal or state health care programs. *Id.*

56. With limited exceptions, the Omnibus Budget Reconciliation Act of 1990 requires a pharmaceutical company to enter into a "rebate agreement" with the U.S. Secretary of Health and Human Services in order to qualify any covered, outpatient prescription drug manufactured by the company for Medicaid payment. 42 U.S.C. §1396r-8(a)(1). Compliance with the rebate agreement is a material condition precedent to Medicaid's agreement to pay claims for the drug. *Id.* The rebate agreement requires each of these drug manufacturers to pay a quarterly rebate directly to each participating state Medicaid program for each of the manufacturer's drugs purchased by that state under its Medicaid plan during the quarter. The rebate must be equal to the difference between the average manufacturer's price ("AMP") and the manufacturer's best price, defined as the lowest price available, anywhere in the nation, from the manufacturer to any non-Medicaid payer, or 15.1% of AMP, whichever is greater. 42 U.S.C. §1396r-8(c)(1). Manufacturers selling covered outpatient drugs paid for by state Medicaid programs must report their AMPs and best prices to the state Medicaid programs on a quarterly basis. 42 U.S.C. §1396r-8(b)(3). The Office of Inspector General of the DHHS has the right to audit the best price and AMP information submitted by the manufacturers. *Id.* The state Medicaid programs report their total Medicaid drugs dispensed in the quarter to each drug manufacturer and the Secretary. 42 U.S.C. 1396r-8(b)(2)(A).

57. The False Claims Act ("federal FCA"), 31 U.S.C. §3729, *et seq*. (prior to May 2009 amendments), imposes civil liability, *inter alia*, on any person who:

(1) knowingly presents or causes to be presented to the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used a false statement to get a false claim paid or approved by the United States; (3) conspires to defraud the government by getting a false or fraudulent claim allowed or paid; or (4) knowingly makes, uses or causes to be made or used a false statement to conceal, avoid or decrease an obligation to pay or transmit money to the United States. The federal FCA defines "knowingly" to include not only acting with actual knowledge of the truth or falsity of claims, but also acting with "reckless disregard" or "deliberate ignorance" of the truth or falsity of claims. The federal FCA provides a remedy of treble damages and mandatory penalties of $5,500 to $11,000 for each violation of the Act.

FACTUAL ALLEGATIONS

58. This lawsuit describes a corporate culture based on achieving astounding revenue growth through drug sales of atypical antipsychotics for non-FDA approved purposes. J&J achieved the largest United States market share for atypical antipsychotícs, both for FDA-approved purposes and for unapproved purposes, through a series of unlawful acts and practices designed to increase drug sales at all costs. Defendants carried out their scheme through the following acts:

- employing the illegal direct solicitation of physicians to prescribe Risperdal® for non-medically accepted indications;

- making false statements to physicians and pharmacists concerning the efficacy and safety of Risperdal® for non-medically accepted indications;

- actively training J&J's employees in methods of avoiding detection of their activities by the FDA;

- entering into illegal kickback and other incentivizing arrangements in order to encourage customers to purchase more drugs for unapproved purposes and help drive end-user demand without the necessary medical indications or proof of efficacy; and

- illegally concealing from federal and state Medicaid programs that the drugs were not medically necessary and that payments made were designed to skirt the Medicaid Drug Rebate Statute, 42 U.S.C. §1396r-8, which was enacted to ensure that Medicaid receives the same discounts and prices on drugs paid by other large public and private purchasers.

59. Risperdal® is a prescription antipsychotic drug belonging to the atypical antipsychotic class. Defendants' scheme consisted of an elaborate and illegal promotion of non-medically accepted indications of Risperdal® in direct contravention of the rules and regulations of the FDA. Risperdal® is one of several modern atypical antipsychotic drugs, as compared to "typical" or the traditional drugs used from the 1950s to the 1990s to treat schizophrenia. Schizophrenia is a complex and challenging psychiatric disorder. It represents a syndrome of disorganized and bizarre thoughts, delusions, hallucinations, inappropriate affect and impaired psycho-social functioning. Fortunately, schizophrenia is somewhat rare, only occurring in approximately 1% of the population.

60. The *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.), assigns a diagnosis of schizophrenia when a patient suffers two or more of the

following characteristic symptoms: delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behavior and negative symptoms. Between the 1950s and 1990s, treatment of schizophrenia relied on antipsychotic drugs that targeted dopamine D2 receptors. The "typical" antipsychotics include chlorpromazine (Thorazine), fluphenzine (Proxilin), haloperidol (Haldol), loxapine (Loxitane), molindone (Moban), mesoridazine (Serentil), perphenazine (Trilafon), thioridazine (Mellaril), thiothixene (Navane), and trifluoperazine (Stelazine).

61. However, typical antipsychotics posed troubling side effects. Excessive blockage of dopaminergic neurotransmission in the basal ganglia causes extrapyramidal syndromes ("EPS") such as parkinsonian effects. A long-lasting movement disorder, tardive dyskinesia ("TD"), also occurs with prolonged treatment. Another negative aspect of typical antipsychotics is that they only partially fulfill their early promise to dramatically improve patients' long-term psychosocial and cognitive disabilities.

62. By the 1980s, clozapine, an atypical antipsychotic, was being investigated for the treatment of schizophrenia on the theory that it might be more effective and cause fewer movement disorders than other antipsychotics. Clozapine was termed an atypical antipsychotic because it had an "atypical index" when measuring its effect on brain activity in certain parts of the brain. It was hypothesized that the different effects by clozapine on the areas of the brain that control movement would cause less movement disorder than the older, typical antipsychotics. However,

the potential of clozapine to cause toxic side effects, including preventing bone marrow from making adequate white blood cells (agranulocytosis), limited its prescription to about 10% of persons with schizophrenia.

63. Clozapine remained the only atypical antipsychotic in the United States market until 1993. Soon thereafter, numerous other atypical antipsychotics were brought to the market, including olanzapine (Zyprexa), quetiapine (Seoquel), Risperdal®, aripiprazole (Abilify), and ziprasidone (Geodon), which were meant to capture the enhanced therapeutic effect of clozapine but without its toxicity and without the increased EPS caused by the older, typical antipsychotics.

64. J&J obtained approval from the FDA to market Risperdal® oral tablets for the management of manifestations of psychotic disorders in adults on December 29, 1993. On June l0, 1996, the FDA approved Risperdal® oral solution for the management of manifestations of psychotic disorders in adults. On March 3, 2002, the FDA corrected the above indications by limiting them to the "treatment of schizophrenia" in adults to accurately reflect the population on which Risperdal® had been tested.

65. The United States Pharmacopeia-Drug Information and the DRUGDEX Information System support the use of Risperdal® for the indications approved by the FDA. The American Hospital Formulary Service Drug Information ("AHFS") supports the use of Risperdal® for the indications approved by the FDA and, in 2003, initiated support for the short-term use of Risperdal® to treat behavioral problems in

children 5 to l7 years old with autistic disorder. The AHFS noted that it did not support the use of Risperdal® to treat the core symptoms of autism, but only manifestations of moderate to severe behavioral problems associated with autistic disorder. Prior to 2003, the AHFS, like the other two compendia, supported only the uses of Risperdal® approved by the FDA. The uses supported by these three compendia and the FDA-approved labeling are collectively defined as "medically accepted indications" in the federal Medicaid Act. 42 U.S.C. §1396r-8.

66. Medicaid reimbursement for drugs is limited to medically necessary prescriptions. Neither the compendia cited above nor the FDA-approved labeling support the use of Risperdal® for treatment of children or adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization. Although Risperdal® is FDA-approved for the treatment of schizophrenia, it is not approved for the treatment of behavioral disorders in patients with dementia. Yet, throughout the history of Risperdal® marketing, from 1994 to the present, marketing campaigns for the drug included promotion for the off-label use of Risperdal® to treat the elderly both for dementia symptoms and for Alzheimer's disease. The decision to target the elderly had two results: (1) medically unnecessary claims for Risperdal® were submitted to Medicaid for reimbursement; and (2) disastrous health consequences befell these elderly Medicaid participants.

67. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of that

drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States government. Accordingly, the sales representatives who market the drug during sales calls to the physicians' offices may not lawfully promote the drug for off-label uses.

68. A well-developed strategy was designed to expand the use of Risperdal® beyond patients with schizophrenia. J&J sought ghost-written research and paid "key opinion leaders" to support various marketing aims. It planned to create a series of studies designed to illustrate Risperdal's® superior profile to a placebo and to a representative conventional antipsychotic. J&J funded the "key opinion leaders" in these trials with the goal of obtaining publication of favorable results. These "key opinion leaders" were nothing more than third-party consultants and researchers who were put on the payroll to support and lend credibility to scientific and marketing goals.

69. In late 1993, Risperdal® became the second atypical antipsychotic to receive FDA approval. In early 1994, Janssen, a subsidiary of J&J, began marketing and selling Risperdal®. During the next few years, Janssen heavily marketed and promoted Risperdal® for its approved indication, treatment of adults with schizophrenia, which accounts for only 1% of the population. It also heavily

marketed Risperdal® for multiple non-approved purposes, including ADHD, depression, anxiety, mood disorder, bipolar disorder, and aggression associated with late-onset dementia, which affect a much greater segment of the population. By late 1996, Janssen had significant market share for U.S. antipsychotic drug use and demonstrated the sales potential of marketing atypical psychotic usage for non-approved indications.

70. In 1999, Janssen was caught by the FDA promoting Risperdal® for the treatment of the elderly. In a letter from the FDA to Todd McIntyre, Janssen's Director of Regulatory Affairs, the agency took issue with certain promotional materials that it had acquired as part of its monitoring and surveillance program. According to the FDA, Janssen engaged in a false and misleading campaign to promote Risperdal® to elderly patients. Among the items found by the FDA in its January 1999 letter to be false and misleading were:

- Janssen's claims in its promotions that Risperdal® was safe and effective for elderly patients, despite little or no data to support such claims;
- Janssen's claims that Risperdal® has a low incidence of movement disorders;
- Janssen's claims that Risperdal® has a low incidence of excessive sedation;
- Janssen's claims that Risperdal® has a low incidence of anticholinergic effects (variety of movement disorder);
- Janssen's claims that Risperdal® treatment is associated with a low incidence of adverse events coupled with the presentation of adverse events in association with the discontinuation of Risperdal® treatment

because such presentation implies that the only adverse events associated with Risperdal® resulted from a patient being taken off the drug;

- Janssen's claims that Risperdal® is safer or more effective than other antipsychotics;

- Janssen's claims that Risperdal® "'enhances daily living'" or that it offers "'quality control of symptoms for daily living'";

- Janssen's claims that Risperdal® can "control health-related quality of life";

- Janssen's failure to warn that the use of Risperdal® by healthy elderly patients creates a greater potential for hepatic and renal dysfunction and cardiovascular sensitivity;

- Janssen's marketing of Risperdal® to indicate that Risperdal® is a safe and effective treatment for hostility in the elderly; and

- Janssen's claims that Risperdal® is a safe and effective treatment for "'psychotic symptoms associated with a broad range of disorders,'" including schizophrenia, schizophrenia form disorder, schizoaffective disorder, bipolar disorder and elderly psychosis.

71. The FDA further found that Janssen's promotion of Risperdal® lacked fair balance because:

- The risk information in its promotional literature "appears in pale and tiny font at the bottom or back of a journal ad or other presentation, or after the closing of a letter," thus lacking the "prominence and readability that is reasonably comparable to the presentation of efficacy information."

- It minimized important information related to TD and EPS.

72. In addition to ignoring direct warnings and/or directives from the FDA and continuing to market Risperdal® for elderly patients without proof of efficacy, Janssen also ignored other known risks of the drug. Medical literature dating as far

back as the 1950s, as well as defendants' own pre-clinical studies of Risperdal®, demonstrate that Risperdal®, like older antipsychotic medications, has the potential to cause diabetes, diabetes-related injuries (*e.g.*, weight gain and hyperglycemia), cardiovascular and cerebrovascular complications, and other severe adverse effects. When Janssen began marketing Risperdal® in 1994, it was aware of the neurochemical bases for the efficacy and side-effects of Risperdal®, *i.e.*, effects on dopamine, serotonin, and histamine systems in the brain. This knowledge should have made Janssen aware of the risk of Risperdal® causing neurological problems, weight gain, diabetes, pancreatitis, hyperglycemia, cardiovascular complications, and metabolic syndrome. Nonetheless, Risperdal's® original label, and all label changes until 2004, failed to warn adequately of these adverse effects.

73. Despite knowledge of the potential for deadly diabetes-related side effects, Janssen chose to conduct the minimum number of clinical trials and to limit each trial's duration to prevent side effects from being revealed.

74. Janssen had actual knowledge that Risperdal® causes weight gain, which significantly increases a patient's risk of contracting diabetes. Despite such knowledge, Janssen failed to include a warning of the potential for weight gain and the possible development of diabetes as a result of the use of Risperdal® in the drug's U.S. labeling for many years. The true safety profile of Risperdal® continued to be concealed in the drug's U.S. labeling, including the risk of diabetes associated with Risperdal®, even though many of the foreign labels had already been changed to

include such a warning. Even after it became clear that Risperdal® was linked to the development of diabetes, Janssen continued to resist changes to its U.S. label.

75. In February 2004, the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists, and the North American Association for the Study for Obesity issued a Consensus Development Statement regarding antipsychotic drugs, obesity and diabetes. Among other things, the Consensus Statement observed that there is "considerable evidence" that treatment with Risperdal® can cause a rapid increase in body weight. The Consensus Statement also observed that numerous case reports had documented the onset and exacerbation of diabetes, including the occurrence of hyperglycemic crises, following the initiation of therapy with many atypical antipsychotics, including Risperdal®.

76. The Consensus Statement acknowledged that diabetes is a very serious disease that afflicts millions of Americans. Some of the more common complications of diabetes are heart disease, stroke, circulatory problems leading to amputation of limbs, neuropathy, and retinopathy. Any drug that both causes the onset of diabetes and exacerbates the complications associated with diabetes in those predisposed to its development poses a very serious health risk. Risperdal® has this risk. Janssen was aware of the public health risk and failed to adequately warn the medical community of the drug's side effects and risks.

77. Janssen never provided a prominent warning about the increased risk of diabetes and hyperglycemia or of the need to provide baseline diabetes screening and glucose monitoring before being forced to do so by the FDA in mid-September of 2003.

78. On September 11, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including Janssen, that, due to an increasing prevalence of diabetes-related illnesses associated with this class of drugs, all labeling must bear the following language in the "WARNINGS" section:

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should

> undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

79. Despite the FDA's mandate that drug manufacturers immediately warn of the dangers described above, Janssen waited two months, until November of 2003, to send prescribing physicians a "Dear Healthcare Provider" letter advising of the new warnings.

80. On April 19, 2004, Janssen's November 2003 letter was chastised by the FDA for being "false" and "misleading." According to the FDA, Janssen's letter misled doctors by:

- failing to disclose the addition of information relating to hyperglycemia and diabetes mellitus on the labeling;
- minimizing the risks of potentially fatal hyperglycemia-related adverse events;
- failing to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible; and
- misleadingly claiming that Risperdal® is safer than other atypical antipsychotics.

81. The FDA demanded that Janssen immediately cease the dissemination of promotional materials for Risperdal® containing claims similar to the foregoing and provide a plan of action to correct the effects of its false and misleading letter.

82. Finally, the FDA admonished Janssen that the violations detailed above did not constitute an exhaustive list, and that it was continuing to "evaluate other aspects" of Janssen's promotional campaign for Risperdal® and could determine that

"additional measures" would be necessary to "fully correct the false or misleading messages resulting from your (Janssen's) violative conduct."

83. Three months later, in July of 2004, Janssen finally sent a "Dear Healthcare Provider" letter that was acceptable to the FDA, which did contain the new warnings. This was ten months after the FDA initially instructed Janssen to adequately warn physicians.

84. In April 2005, the FDA determined that the treatment of behavioral disorders in elderly patients with dementia with atypical antipsychotic drugs is associated with increased mortality. In a total of 17 placebo-controlled trials performed with atypical antipsychotics, including Risperdal®, in elderly dementia patients with behavioral disorders, 15 of these trials revealed increases in mortality in the drug-treated group compared to the placebo-treated patients. Examination of specific causes of death revealed that most were due to either heart-related events, such as heart failure and sudden death, or infections, such as pneumonia.

85. As a result of these findings, the FDA required J&J to include a "black box warning" in their labeling describing this risk and emphasizing that Risperdal® is not approved for these conditions. Notably, a similar black box warning was not required on older, typical antipsychotics.

86. In September of 2005, the public perception of Risperdal® was dealt a crushing blow when the results of the Clinical Antipsychotic Trials of Intervention Effectiveness ("CATIE") study were published in the *New England Journal of*

Medicine. The CATIE study was initiated by the National Institute of Mental Health ("NIMH") to compare the relative efficacy of four newer, atypical antipsychotics to each other and to an older, typical antipsychotics. The study was conducted between January 2001 and December 2004 at multiple clinical sights across the United States.

87. The CATIE study grew out of concerns that had emerged regarding the safety and value of atypicals. Earlier clinical trials seemed to indicate that Clozapine is more effective than typical antipsychotic drugs; however, the issue whether the other atypicals – like Risperdal® – were more effective than the cheaper typical antipsychotic drugs remained largely unanswered. Therefore, the NIMH undertook this multi-site, double-blind comparison between an older typical antipsychotic drug, perphenazine, and newer atypical antipsychotic drugs, including Risperdal®.

88. The CATIE results were revolutionary. Regarding efficacy, the study's authors concluded that Risperdal® is no more effective than the typical antipsychotic, perphenazine, in treating schizophrenia. In addition, the times to discontinuation because of intolerable side effects, including movement disorders, were similar among all the groups. In other words, the CATIE study proved what defendants knew since launching Risperdal®: (l) that Risperdal® is no more effective in treating schizophrenia than the older antipsychotics; (2) that Risperdal® is no safer than the older antipsychotics; and (3) that Risperdal® has intolerable side effects making it no more desirable than the less expensive older antipsychotics.

89. The CATIE study marked the first time such negative information about the safety and efficacy of Risperdal® became public. In large part, this is because the CATIE study was an independent evaluation of available medications, while all of the prior comparisons of Risperdal® to older, typical antipsychotics were controlled by defendants.

The Kickback Scheme

90. Despite the 1999 FDA letter admonishing Janssen for improperly promoting Risperdal® for elderly patients suffering from dementia, J&J continued to promote Risperdal® for elderly patients despite studies and data that confirmed the lack of efficacy and significant health and safety risks associated with the use of Risperdal® by the elderly.

91. To accomplish this, Omnicare, the largest nursing home pharmacist in the United States, was used to market Risperdal® to elderly patients who suffered from dementia. Omnicare provides pharmaceuticals and related pharmacy and ancillary services to long-term health care institutions. Among the services that Omnicare engages in is the delivery of drugs to patients in nursing homes.

92. After Omnicare delivers drugs to patients, it submits reimbursement claims on behalf of those patients to their insurers. Omnicare submits approximately 65% of these claims to Medicaid.

93. Omnicare also employs hundreds of "consultant pharmacists." Consultant pharmacists make recommendations to nursing home physicians about the

drugs they should prescribe to nursing home residents. Consultant pharmacists became necessary after Congress decided to act to prevent the excessive use of antipsychotic drugs.

94. Under the amendment to the Social Security Act:

> Psychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan (included in the written plan of care described in paragraph (2)) designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs.

42 U.S.C. §1396r(c)(1)(D).

95. The DHHS implemented this amendment to the Social Security Act by mandating that a licensed pharmacist review the drug regimen of each resident and report any irregularities to the attending physician. During this review, the consultant pharmacists make recommendations to remove, change, or add medications. Omnicare (and J&J) refer to consultant pharmacists efforts to obtain physician authorization to switch nursing home patients from one drug to another as an "intervention."

96. J&J essentially considered Omnicare's pharmacist consultants a branch of their marketing department.

97. J&J and Omnicare both used the term "intervention" to refer to the process in which Omnicare pharmacists and consultant pharmacists obtained physician authorization to switch nursing home patients from one drug to another.

During much of the 1999 through 2004 time period, Omnicare's primary intervention was to drive prescriptions of Risperdal®, which was used at nursing homes as a chemical restraint. The goal was to increase spending by Medicaid and other federal health care programs on J&J drugs.

98. Defendants and other J&J employees understood that it was a violation of the anti-kickback statute to offer or to pay remuneration, by whatever means, to induce a customer like Omnicare to purchase or to recommend J&J drugs. Likewise, defendants and other J&J employees responsible for handling the Omnicare account understood that J&J could violate the law by using payments to customers for data as a substitute for discounts or rebates that, if disclosed, could increase J&J's financial obligations to the Medicaid program. It was understood that it would be a kickback to pay a customer like Omnicare for the sake of fostering a relationship or for good will, where the goal was always to convince Omnicare to purchase and to recommend J&J drugs.

99. It was a violation of the statute to pay Omnicare rebates to switch patients to J&J drugs, making payments to Omnicare for data (that J&J was not actually receiving) as a substitute for rebates or discounts, and paying Omnicare various grants and sponsorship fees whose purpose was to induce Omnicare to purchase and to recommend J&J drugs.

100. The drug supply agreement in place between J&J and Omnicare in 1999 was signed on April 8, 1997, and had an ostensible term of April 1, 1997 to March 31,

2000 (hereinafter, the "1997 Agreement"). The 1997 Agreement provided for J&J to sell Omnicare certain drugs, including Risperdal®, Propulsid, Levaquin, Procrit, Duragesic, and Ultram, and for J&J then to pay Omnicare quarterly market share rebates, where the percentage amount of the rebate on each drug increased as market share of that drug increased, and market share was determined based on Omnicare's purchases of each drug in comparison to Omnicare's purchases of competing products.

101. In May 1999, J&J and Omnicare signed a 5-year performance contract which provided "incentives to Omnicare to advocate appropriate use of J&J products." These incentives turned out to be very valuable as a tool for J&J to drive sales through Omnicare. For example "a $3MM investment in rebates with Omnicare," allowed J&J to gain "$9MM in sales." J&J understood that rebates were very important to Omnicare and represented approximately 60% of Omnicare's net income.

102. In March 2000, J&J and Omnicare signed a new drug supply agreement with an ostensible term from April 1, 1999 to March 31, 2004 (hereinafter, the "2000 Agreement"). In similar fashion to the 1997 Agreement, the 2000 Agreement provided for J&J to sell certain drugs to Omnicare, and for J&J to pay Omnicare market share rebates and an additional 2% "Annual Product Performance Incentive." The 2000 Agreement included a "Schedule of Qualifying Active Intervention Programs" for specific drugs, including Risperdal®.

103. During the period from 1999 through 2004, J&J paid Omnicare tens of millions of dollars in market share rebates pursuant to the 1997 Agreement and the 2000 Agreement. In many instances, at Omnicare's request, J&J paid quarterly rebates to Omnicare in advance, thus effectively providing Omnicare with interest-free loans of millions of dollars.

104. Congress enacted the Medicaid Drug Rebate Statute, 42 U.S.C. §1396r-8, to ensure that the Medicaid program would receive the benefit of the same discounts and prices on drugs that other large public and private purchasers enjoyed. *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Under the Medicaid Drug Rebate Statute, in order for a brand name drug, such as Risperdal®, to be covered and reimbursed by the Medicaid program, its manufacturer has two primary obligations. First, the manufacturer must report on a quarterly basis to the Secretary of DHHS the drug's AMP and the best price offered for that drug. 42 U.S.C. §1396r-8(b)(3)(A). Second, the manufacturer must pay each state a quarterly rebate equal to the total number of drug units (*e.g.*, pills) purchased by the state times the greater of (1) 15.1% of the drug's AMP, or (2) the difference between the AMP and the best price. 42 U.S.C. §1396r-8(c)(1)(A). In other words, for a drug like Risperdal®, J&J was required to pay at least a 15.1% rebate to each state on all of its Risperdal® sales for Medicaid patients, but J&J would have to pay a higher Medicaid rebate on all of those sales if it offered any single customer, *e.g.*, Omnicare, a total discount that exceeded 15.1%.

105. During the late 1990s and early 2000s, J&J rarely, if ever, reported a quarterly "best price" for Risperdal® that reflected total discounts in excess of the minimum 15.1% rebate J&J was required to pay to the state Medicaid programs. In 1999, the concern arose that, combined with the up-front discounts on Risperdal® J&J was giving to Omnicare, the additional quarterly rebates J&J owed to Omnicare would set a new best price that J&J would have to report to the Medicaid program because of the rebates paid to Omnicare. As of September 1999, Omnicare was taking the position that J&J owed it approximately $700,000 in 1998-1999 rebates that defendants did not want to pay because of best price concerns.

106. In or about October 1999, J&J began discussing with Omnicare the concept of J&J paying Omnicare for data identifying physician prescribers of antipsychotics in lieu of paying Omnicare the hundreds of thousands of dollars in rebates Omnicare believed it was owed. In seeking to justify this data purchase concept internally, J&J's Omnicare sales team noted that "Johnson & Johnson believes [Omnicare] to be the gold standard of Pharmacy Providers" and that Omnicare had "been able to switch propoxyphene prescriptions to Ultram and ha[d] done an outstanding job in generating Risperdal market share."

107. J&J expressed concern about the legality of paying for data in lieu of paying a rebate in connection with a dispute over rebates Omnicare claimed it was owed for an earlier period (from the second quarter of 1997 to the first quarter of 1998). In order to resolve the dispute with Omnicare over rebates allegedly owed for

the fourth quarter of 1998 and the first quarter of 1999, J&J continued to pursue the concept of purchasing data from Omnicare pursuant to a "Consulting & Services Agreement." J&J viewed such an agreement as a means of "assisting [Omnicare] financially" with "some of the non market share activities that they do on our behalf," including "[c]ommunicating J&J promotions to nursing home[s] that they serve."

108. As the process evolved, J&J began to consider having the total amount of data fee payments increased in order to serve as a substitute not only for the rebates from the fourth quarter of 1998 and the first quarter of 1999, but also for additional rebates in the form of the ongoing 2% Annual Product Performance Incentive (also referred to as a "strategic overlay") on Risperdal® that J&J was required to pay under the 2000 Agreement. As with the rebates Omnicare was claiming for the fourth quarter of 1998 and the first quarter of 1999, J&J did not want to pay the strategic overlay in the 2000 Agreement because they feared the additional 2% discount on Risperdal® would set a lower best price on Risperdal®, and thus would substantially increase J&J's overall Medicaid rebate liabilities to the states.

109. J&J and Omnicare signed their Consulting & Services Agreement in October 2000. The agreement had a term of July 1, 2000 to April 1, 2004, and called for J&J to pay Omnicare $450,000 for the first three-month period of the term, and then $300,000 per quarter thereafter, for a total of $4,650,000. In exchange, Omnicare was to provide the following:

A. ***Physician Prescribing Report by Strategic Brand*** – **[Quarterly]** This national report will list 200 competitive prescribing physicians for each J&J Strategic Brand (RISPERDAL® risperidone, DURAGESIC® fentanyl transdermal system, and ACIPHEX™ rabeprazole, LEVAQUIN TABS® levoflaxacin, LEVAQUIN IV® levoflaxacin, and ULTRAM® tramadol) and the preferred product of such physicians. This report will be provided by Omnicare's national clinical director.

B. ***Competitive Market Share Report by Pharmacy Site*** – **[Quarterly]** This report will list Days of Therapy (DOT) market shares at each Omnicare pharmacy site for the following J&J products and their relative competitive products as defined by their respective J&JHCS Defined Markets: Risperdal, Duragesic, Aciphex, Ultram, Levaquin and Levaquin IV.

C. ***Market Share Report by Pharmacy Site*** – **[Monthly]** This report will list DOT market shares at each Omnicare pharmacy site for the following J&J products as defined by their respective J&JHCF Defined Markets: Risperdal, Duragesic, Aciphex, Ultram and Levaquin.

110. At exactly the same time J&J and Omnicare signed the Consulting & Services Agreement, they also signed an amendment to the 2000 Agreement removing Risperdal® from the 2% strategic overlay.

111. To justify the legality of the Consulting & Services Agreement internally, J&J purportedly conducted a "fair market value" analysis of the data it agreed to purchase. In reality, however, Omnicare never supplied much of the data J&J had agreed to purchase, and J&J never demanded it. Neither Omnicare's national clinical director nor any other Omnicare employee ever supplied J&J with any quarterly lists of "200 competitive prescribing physicians for each J&J Strategic Brand . . . and the preferred product of such physicians," as part A of the Consulting & Services Agreement required. Instead, as had been the case prior to the signing of the

Consulting & Services Agreement, local Omnicare pharmacy sites occasionally supplied local J&J sales representatives with names of prescribing physicians. As a J&J National Account Director later observed, the Omnicare pharmacies did so "randomly" and "generally not . . . willingly."

112. Even though Omnicare did not provide the data it was contractually obligated to provide in the Consulting & Services Agreement, J&J paid Omnicare as specified under the agreement. Each payment was referred to as a "marketing fee" and J&J cautioned Omnicare that "some or all of this amount may be considered a Discount which Omnicare may have an obligation to reflect in any cost report or claim for reimbursement with Medicare/Medicaid," even though J&J itself did not treat the payments as discounts and did not disclose them to Medicaid.

113. J&J supplemented its rebate and data fee kickbacks to Omnicare by paying various other kickbacks in the form of "grants," "educational funding," and meeting sponsorship fees.

114. The Consulting & Services Agreement in 2000 was not the first time J&J did not pay Omnicare discounts or rebates that would have affected the Medicaid best price of Risperdal®. In mid-1999, there became at issue approximately $300,000 to satisfy Omnicare's claim under the 1997 Agreement's 1% strategic overlay provision for the period from the second quarter of 1997 to the first quarter of 1998.

115. Instead of J&J paying $300,000 to Omnicare as a strategic overlay (which would have been reportable to Medicaid for best price purposes), J&J and

Omnicare agreed that J&J would pay Omnicare $300,000 for "educational funding." J&J then sent a letter to Omnicare enclosing written agreements pursuant to which J&J would pay Omnicare $300,000 to support a "program in helping Omnicare's consultant pharmacists overcome objections from physicians. This program will be especially effective in overcoming obstacles pertaining to resistance in prescribing Risperdal."

116. In mid-October 1999, J&J and Omnicare formally entered into an "Initiative Partnership Agreement" pursuant to which J&J paid Omnicare $300,000 "to partially defray the cost to Omnicare in developing and marketing mutually acceptable broad-based formulary intervention initiatives, and to assist Omnicare consultant pharmacists overcome obstacles and objections they encounter in implementing intervention programs." In other words, rather than paying Omnicare a $300,000 strategic overlay under the 1997 Agreement, J&J instead paid Omnicare $300,000 in "educational funding" for the express purpose of inducing Omnicare to recommend that physicians prescribe Risperdal® for their nursing home patients.

117. **J&J's "ReView" Grants to Omnicare**. During the early 2000s, Omnicare raised money from numerous drug manufacturers for its so-called "ReView" program. The ostensible purpose of the program was to develop "health management" programs that would identify nursing home patients for whom additional drugs could be prescribed. In a memorandum to Omnicare's Chief Executive Officer, Omnicare's Senior Vice President of Professional Services and

Purchasing referred to the ReView program as the "'one extra script per patient (ReView) program.'" One of the Omnicare ReView health management programs was "Behavior Management in Dementia – encompassing the appropriate use of antipsychotics and going from the typical to the newer and better tolerated atypical antipsychotics."

118. In January 2000, Omnicare requested that J&J make a $50,000 grant for the ReView program. In response, J&J made $251,000 in ReView grants to Omnicare during 2000. In 2001, J&J observed that Omnicare's ReView program had "[g]enerated over 11,000 new prescriptions for antipsychotics."

119. As noted above, during the 1999 to 2004 period, Omnicare's annual purchases of J&J drugs nearly tripled to almost $300 million. This increase in purchases reflected increased prescribing of J&J drugs by physicians at nursing homes served by Omnicare, which in turn reflected the numerous "intervention" efforts Omnicare undertook in response to the kickbacks it received.

120. Even though Congress expressed clear concerns about the use of antipsychotics in nursing homes, and even though there is an intrinsic clinical risk in switching a stabilized patient from one antipsychotic to another, in exchange for J&J's payments, Omnicare devoted substantial effort to its intervention for Risperdal®. Both Omnicare and J&J referred to this effort as Omnicare's "Risperdal Initiative." The goal of the Risperdal Initiative was to generate as many Risperdal® prescriptions as possible.

121. The Risperdal Initiative began in 1997, after J&J and Omnicare entered into the 1997 Agreement. In order to implement it, Omnicare distributed to all of its pharmacists around the country a so-called Patient Specific Therapeutic Interchange Protocol for Risperdal® (the "Risperdal PSTI"). In the 1998 version of the Risperdal PSTI, Omnicare provided its pharmacists with suggested oral statements and written comments to use to encourage physicians to prescribe Risperdal®, sometimes regardless of whether a given patient was already stabilized on another antipsychotic.

122. In a summer 2000 memorandum, a J&J employee observed that Omnicare's ongoing Risperdal Initiative "has generated an all time market share high of 55.5% throughout the 1st quarter of 2000. This market share represents Omnicare[']s ability in persuading physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia." By the following spring, Omnicare had driven Risperdal's® share of Omnicare's antipsychotic utilization to 58.5%.

123. Another means by which Omnicare implemented the Risperdal Initiative was through Physician Authorization Letters, or "PALs." Through PALs, Omnicare encouraged the substitution of medication to occur at the pharmacy level. The initiative included requesting a substitution to Risperdal® from any new prescription of Zyprexa or Seroquel.

124. In 2002, J&J's Long-Term Care Group reported that, in a recent meeting, Omnicare's Director of Clinical Operations had "stressed that Risperdal is their primary intervention."

125. J&J employed other tactics involving off-label promotion and marketing to drive Risperdal® sales. Beginning in 2002, J&J funded a research center for child psychopathology at Massachusetts General Hospital, run by Dr. Joseph Biederman, "to move forward the commercial goals of J.&J." Dr. Biederman's work helped to fuel a forty-fold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children.

126. J&J's support for Dr. Biederman's work was not limited to funding. *The New York Times* further reported that internal J&J "documents also show that the company prepared a draft summary of a study that Dr. Biederman, of Harvard, was said to have written." According to the article:

> A June 2002 e-mail message to Dr. Biederman from Dr. Gahan Pandina, a Johnson & Johnson executive, included a brief abstract of a study of Risperdal in children with disruptive behavior disorder. The message said the study was intended to be presented at the 2002 annual meeting of the American Academy of Child and Adolescent Psychiatry.
>
> "We have generated a review abstract," Dr. Pandina wrote, "but I must review this longer abstract before passing this along."
>
> One problem with the study, Dr. Pandina wrote, is that the children given placebos and those given Risperdal both improved significantly. "So, if you could," Dr. Pandina added, "please give some thought to how to handle this issue if it occurs."

> The draft abstract that Dr. Pandina put in the e-mail message, however, stated that only the children given Risperdal improved, while those given placebos did not. Dr. Pandina asked Dr. Biederman to sign a form listing himself as the author so the company could present the study to the conference, according to the message.

127. As reported in the article, not only did J&J deliberately act to stimulate demand for off-label uses of Risperdal® in children by funding and ghost writing for Dr. Biederman, J&J also paid him to make misleading presentations concerning the results of clinical studies.

128. The March 10, 2010 *Bloomberg.com* article further reports that J&J, through its Janssen subsidiary,

> sought to sell Risperdal for bipolar disorder, dementia, mood and anxiety disorders and other unapproved uses, the documents show. Sales exceeded Janssen's expectations, according to the plans. Though Janssen predicted in 1993 it would take seven years to reach $295 million, U.S. sales hit $343 million in 1995.
>
> Hundreds of Janssen salespeople sold to doctors, nursing homes, Veteran's Administration facilities and jails, the records show. Marketers gave doctors materials about studies of unapproved uses for Risperdal. Janssen sponsored clinical trials of the drug's effect on other illnesses.
>
> In 1994, 1999 and 2004, the FDA ordered Janssen to stop making false and misleading marketing claims about Risperdal's superiority.
>
> Janssen set sales goals for 2000 of $302 million for geriatric sales, or 57 percent of the market, and $175 million in bipolar sales, or 32 percent, according to the business plan. That same year, Janssen planned to expand its geriatric sales force by 50 to 136 people, according to the business plan.
>
> It wasn't until 2003 that the FDA approved Risperdal for bipolar disorder. In 2006, the regulator approved it for symptoms related to

> autism in children and teens. The FDA approved it to treat bipolar children and teens the next year.
>
> The drug was never approved for dementia.

129. Under the federal FCA, knowingly presenting or causing to be presented to the United States any false or fraudulent claim for payment is a violation of federal law. Knowingly includes making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the government. "Claim" includes any request or demand, whether under contract or otherwise, for money or property which is made to a contractor grantee or other recipient if the United States government provides any portion of the money or property which is requested or demanded, or if the government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. The United States may recover for a violation of the federal FCA three times the amount of the damage the government sustained and a civil monetary penalty.

130. As a result of these secret and illegal transactions, J&J knowingly caused Omnicare to submit claims to state and federal officials administering the Medicaid program that were false because Omnicare, as a recipient of illegal kickbacks from J&J, was ineligible to seek payment of Medicaid funds and made false statements to Medicaid concerning their best prices to customers to avoid payment of rebates owed Medicaid under the Medicaid rebate program, 42 U.S.C. §1396r-8, and making false statements to government payers concerning their best prices to get false claims paid.

131. The actions were taken by Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil") at the corporate strategy level to increase sales of Risperdal® for non-medically indicated conditions and symptoms and, as a result, to inappropriately obtain Medicaid payments for these off-label prescriptions.

132. Under the federal anti-kickback law, 42 U.S.C. §1320a-7b(b), it is illegal to offer, receive, or solicit any remuneration, kickback, bribe or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order to induce such person to purchase, lease or order, or to arrange for or recommend the purchasing, leasing or order of any goods, service or item for which payment may be made in whole or in part under a government health care program.

133. A violation of the anti-kickback statute can subject the perpetrator to exclusion from participation in federal health care programs. Such an exclusion would result in catastrophic damages to the Company and its shareholders because Medicaid and Medicare would no longer cover the costs of any J&J drug. Without Medicaid or Medicare coverage most patients would not use J&J drugs.

The Scheme Is Revealed and Omnicare Pays a $98 Million Fine

134. On November 3, 2009, the DOJ announced that Omnicare agreed to pay $98 million to resolve allegations that it solicited and received kickbacks from J&J in exchange for recommending Risperdal®.

135. Omnicare allegedly engaged in illegal conduct with J&J. From January 1999 through December 2004, Omnicare knowingly submitted, or caused to be

submitted, false or fraudulent claims to Medicaid for Risperdal®. The claims were false or fraudulent because they resulted from payments that Omnicare solicited and received from J&J, from 1999 through 2004, in violation of the anti-kickback statute. The payments included: (a) quarterly rebate payments on Omnicare's purchases of Risperdal® under the rebate agreements executed in April 1997 and March 2000 where the rebate agreements conditioned payment of the rebates upon Omnicare engaging in an "active intervention program" to convince physicians to prescribe Risperdal® and requiring that all competitive antipsychotic products be "Prior Authorized for Risperdal® failure," and where Omnicare failed to disclose to physicians that such intervention activities were a condition of it receiving such rebate payments; and (b) payments ostensibly for the purpose of purchasing prescribing data from Omnicare, making educational grants, and sponsoring and attending Omnicare meetings, when in fact one purpose of the payments was to induce Omnicare to recommend that physicians prescribe Risperdal® to their nursing home patients, including patients covered by Medicaid. *See* Settlement Agreement dated November 2, 2009 between the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, Omnicare, Inc., and the Relators, at §II.I.4.

The DOJ Complaint

136. On January 15, 2010, the DOJ intervened in a *qui tam* suit against the Company and filed its own complaint in the District of Massachusetts alleging that

J&J engaged in a 5-year scheme to cause Omnicare to push J&J drugs Risperdal® and Levaquin® (the "DOJ Complaint").

137. According to the DOJ Complaint, J&J's kickbacks induced Omnicare to purchase, order, or recommend J&J drugs in violation of the federal anti-kickback statute. In addition, the DOJ Complaint states that J&J knowingly caused Omnicare to make or use false records material to false or fraudulent claims paid or approved by the government in violation of the federal FCA. J&J also violated the federal FCA by conspiring with Omnicare to pay Omnicare kickbacks in violation of the federal anti-kickback statute. The DOJ is seeking to recover treble damages plus a civil monetary penalty for each false claim. The DOJ is also seeking to recover all amounts J&J was unjustly enriched by as a result of the illegal kickback scheme.

Civil Actions Against J&J Based on Its Scheme with Omnicare

138. In addition, a purported class action was filed against the Company on behalf of all nursing home residents and/or the estates of all nursing home residents who received drugs and/or services from Omnicare and/or any of its direct subsidiaries who were dispensed Risperdal®, Ultram®, Levaquin®, Duragesic®, or Procrit® and who paid money, who incurred a obligation for charges or whose benefits providers paid money on their behalf for those drugs from April 1, 1997 to the present. According to the class action complaint, Omnicare and J&J's conspiracy continues to this date. The class action alleges J&J violated federal antitrust laws.

Topamax

139. Civil actions tied to off-label marketing have increased in the past four years. Drug companies have paid huge settlements. For example, in September 2009, Pfizer agreed to pay the U.S. government and several states $2.3 billion for its off-label promotion of its Bextra medication and other drugs. For antipsychotic medications alone, off-label settlements against Pfizer, Eli Lilly, AstraZeneca and Bristol-Myers Squibb have amounted to over $2.5 billion since 2006.

140. As reported in the Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed on March 11, 2004 and signed by defendants Weldon, Darretta, Coleman, Cullen, Langbo, Linquist, Mullin, Satcher and Schacht, the Company has been under investigation for off-label promotion of Topamax since at least December 2003. That filing disclosed that "on December 8, 2003, the Company's Ortho-McNeil Pharmaceutical unit received a subpoena from the United States Attorney's office in Boston, Massachusetts seeking documents relating to the marketing, including alleged off-label marketing, of TOPAMAX."

141. Further, on July 27, 2004, the Company received a letter request from the New York State Attorney General's Office for documents pertaining to marketing, off-label sales and clinical trials for Topamax (along with Risperdal®, Procrit, Reminyl, Remicade and Aciphex). This additional investigation into off-label marketing and sales of Topomax was disclosed in the Company's Annual Report on Form 10-K for the fiscal year ending January 2, 2005, filed March 15, 2005, and

signed by defendants Weldon, Darretta, Coleman, Cullen, Langbo, Lindquist, Mullin, Satcher and Schacht.

142. Three years later, and despite the fact that defendants were aware of the governmental investigations into the Company's sales and marketing practices across a wide spectrum of drugs, including but not limited to Topamax, by at least early 2004, the Company received yet another subpoena in March of 2007. This subpoena was from the U.S. Attorney's Office in Boston, and requested information not only regarding the sales and marketing of Topamax, but also regarding the Company's corporate supervision and oversight of Ortho-McNeil, the subsidiary charged with selling Topamax. The facts surrounding this additional subpoena were disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 30, 2007, filed February 26, 2008, and signed by defendants Weldon, Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, and Satcher.

143. The March 2007 subpoena was part of a coordinated investigation involving three separate U.S. Attorney's Offices, spanning three J&J subsidiaries and involving three different drugs, focused on J&J's lack of corporate supervision and oversight of the three subsidiaries (Janssen, Ortho-McNeil and Scios) involved in the promotion, sales and marketing of Topamax, Risperdal® and Natrecor. According to the Company's most recent Annual Report on Form 10-K for 2009, filed March 1, 2010, prosecutors in the Topamax investigation have sought grand jury testimony by J&J employees.

144. Topamax was first approved by the FDA in December 1996 for the treatment of seizures. In August 2004, the FDA approved Topamax for the prevention of migraines. Despite these limited indications, pursuant to the Topamax off-label promotion scheme, J&J successfully generated substantial off-label demand for the drug.

145. As a result of this scheme, Topamax has been prescribed extensively for numerous off-label indications, including treatment of bipolar disorder, to counteract weight gain associated with numerous antidepressants, treatment of alcoholism, treatment of obesity, treatment of binge eating, treatment of posttraumatic stress disorder, treatment in the prevention of periventricular leukomalacia in preterm infants after an hypoxic-ischemic injury, the treatment of essential tremor, bulimia nervosa, obsessive-compulsive disorder, smoking cessation, idiopathic intracranial hypertension, neuropathic pain, cluster headache, and cocaine dependence. An analysis reported by *Knight-Ridder* in 2003 found that 79% of all prescriptions for Topamax were for off-label uses.

146. Topamax sales grew explosively, from $687 million in 2002 to over $2.7 billion in 2008, the year before its patent expiration.

147. In September 2004, J&J received a Warning Letter from the FDA concerning a serious violation of law by J&J in its marketing materials for Topamax. This letter was copied to defendant Weldon, Chairman of the Board and CEO of J&J. The Warning Letter stated that the Company's Topamax promotional materials "fail

to present any information about the risks of oligohidrosis, hyperthermia, and metabolic acidosis."

148. The September 2004 Warning Letter went on to emphasize that "[i]t is also noteworthy that the majority of reports of these adverse reactions have been in children," and demanded that J&J withdraw these false and misleading promotional materials from circulation and respond with a plan of action to disseminate complete Topamax risk information to the audiences exposed to the misleading materials.

149. The Company's failure to warn patients and prescribers about these "very serious risks" of treatment with Topamax is yet another example of the defendants' policy to avoid, delay, or minimize taking patient safety actions that could adversely affect pharmaceutical sales, thus elevating commercial goals over issues of patient health benefits and patient health risks.

150. Despite the knowledge by the Board since 2003 of the federal investigation of the Company's illegal off-label promotion of Topamax, J&J continued with its aggressive efforts to generate off-label demand for the drug at least into late 2007.

151. As noted above, in addition to the long-running federal investigation of J&J's off-label promotion of Topamax, the Company has also been charged with disseminating false and misleading promotional materials omitting required disclosures of serious health risks associated with the use of Topamax.

152. In late April 2010, two subsidiaries of J&J settled all claims with the federal government. The subsidiaries agreed to pay $81.51 million in fines and pleaded guilty to a misdemeanor crime for misbranding the drug.

PROXY ALLEGATIONS

The Individual Defendants Cause J&J to Disseminate Materially Inaccurate Proxy Statements

153. J&J's Annual Proxy Statements filed with the SEC on Form DEF 14A on or about March 12, 2008, March 11, 2009 and March 17, 2010 (the "Proxy Statements"), were materially inaccurate in that they failed to disclose numerous highly material facts and circumstances. The materially inaccurate Proxy Statements caused direct harm to the Company in that, among other things, the omissions hid the systematic legal violations that occurred within the Company. These illegal actions resulted in the *qui tam* actions, in which the DOJ subsequently intervened.

154. Each of the Proxy Statements was intended to, and did, procure J&J's shareholders' votes with respect to matters materially affecting the Company that legally required shareholder approval. The Proxy Statements sought and obtained election of members of the Board by shareholder vote, in each case upon the Board's explicit recommendation as to which directors should be elected.

155. Each director on the Board was duty-bound – pursuant to their general fiduciary duties under New Jersey law, the specific duties applicable to directors set forth in the Company's foundational corporate documents, and by the clear provisions

of the federal securities laws – to fully disclose all information material to shareholders' decision concerning how to cast their votes in connection with the election of Board members in 2008, 2009, and 2010.

156. Despite its fiduciary duty and its obligations under the federal securities laws, the Board caused the Company to file and disseminate the materially inaccurate Proxy Statements. Specifically, J&J's definitive Proxy Statements provided materially similar information and disclosures concerning the Company, the general responsibilities of the Board and its committees, and the basis upon which the members of the Board (or prospective members of the Board) were seeking election to another (or initial) term of office. In addition, J&J mailed the Proxy Statements to shareholders concurrently with the mailing of the Company's annual financial report. However, the Proxy Statements uniformly failed to disclose material information to shareholders concerning critical aspects of the Board's responsibilities and activities – such as the Board's obligation to assure compliance with applicable drug marketing laws and regulations, or the fact that the financial and operating metrics disclosed in the Proxy Statements were the result of widespread misconduct within J&J that the Board was duty-bound to prevent.

157. The 2008, 2009 and 2010 Proxy Statements were materially inaccurate and incomplete, because they failed to disclose that the Company reaped hundreds of millions of dollars in ill-gotten gains as a result of illegal kickbacks paid to Omnicare,

and that the Company faced hundreds of millions of dollars in exposure from civil actions.

158. In light of the material omissions from the Proxy Statements, the votes and the consequent election of directors to the Board were obtained on the basis of inaccurate disclosures. Had shareholders been provided with complete and accurate information concerning the Board's performance of its duties – including with respect to presiding over the Company's extensive violations of applicable laws – the members of the Board would not have been elected (or reelected).

159. The election (or reelection) of the Board members inflicted significant harm on the Company. In essence, the Board members' failure to actually perform the affirmative legal and compliance obligations directly caused and perpetuated the Company's continued violation of the drug marketing rules. In addition, instead of settling with the government as Omnicare did, the Board has directed J&J to fight the charges and thereby expose the Company to treble damages and the possibility of no longer being able to participate in Medicaid or Medicare. The Board's assumption of affirmative compliance duties under applicable laws was directly relied upon by others – such as federal regulators and the Company's shareholders – who, based on that reliance, refrained from taking action to terminate the Company's systematic legal violations. This reliance on the Board's assumption of duty caused direct detriment to the Company, which, in the absence of the Board's fulfillment of its obligations, was left helpless to prevent the misconduct occurring in its name.

160. Accordingly, J&J has been damaged by the materially inaccurate statements in the 2008, 2009, and 2010 Proxy Statements that procured the election and/or reelection of certain of the director defendants.

DAMAGES TO J&J

161. As a result of the Individual Defendants' improprieties, J&J has expended and will continue to expend significant sums of money. Such expenditures include, but are not limited to:

(a) rebates paid to Omnicare in violation of applicable laws;

(b) costs incurred in investigating the complaints of wrongdoing made by the whistleblowers and governmental agencies;

(c) costs incurred in defending J&J in the whistleblower and subsequent DOJ litigation concerning the illegal rebate practices, plus potentially hundreds of millions of dollars in settlement or to satisfy an adverse judgment, including the $81 million paid in connection with the misbranding and illegal promotion of Topamax;

(d) costs incurred in defending J&J in the consumer class action, plus potentially hundreds of millions of dollars in settlement or to satisfy an adverse judgment; and

(e) costs incurred from compensation and benefits paid to the Individual Defendants, who as directors and/or officers have breached their duties to J&J.

162. Moreover, these actions have irreparably damaged J&J's corporate image and goodwill.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

163. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

164. During all times relevant hereto, the Individual Defendants, collectively and individually, initiated a course of conduct that was designed to and did: (i) conceal the fact that they had caused the Company to engage in violations of federal anti-kickback and rebate laws, as well as the illegal off-label marketing of its drugs; (ii) enhance the Individual Defendants' executive and directorial positions at J&J and the profits, power, and prestige that the Individual Defendants enjoyed as a result of holding these positions; and (iii) deceive the public, including J&J's own shareholders, via false and misleading proxy statements, regarding the Individual Defendants' management of J&J's operations, the Company's adherence to applicable laws, and its future business prospects. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants, collectively and individually, took the actions set forth herein.

165. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

General Derivative Allegations

166. Plaintiff incorporates by reference and re-alleges each and every allegation set forth herein.

167. Plaintiff brings this action derivatively in the right of and on behalf of J&J to redress injuries suffered, and to be suffered, by J&J as a direct result of breaches of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment, as well as the aiding and abetting thereof, by the Individual Defendants. J&J is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

168. Plaintiff will adequately and fairly represent the interests of J&J in enforcing and prosecuting its rights.

169. Plaintiff was an owner of J&J stock at all times relevant to the wrongful course of conduct alleged herein, and remains a shareholder of the Company.

Pre-Suit Demand Is Futile

170. As set forth below, by virtue of: (1) the long-running nature of the wrongdoing; (2) defendants' tenures on the Board and Committees which were designed to monitor and ensure J&J's (and its subsidiaries') compliance with federal and state regulations and law; and (3) defendants' signing of Company filings (including Annual Reports) which acknowledged extensive and lengthy investigations into business practices across different products, defendants were aware of both the Risperdal® kickback scheme and the off-labeling marketing schemes.

Current Board

171. The J&J Board currently consists of the following ten individuals: defendants Coleman, Cullen, Johns, Lindquist, Mullin, Perez, Prince, Satcher, Weldon, and non-defendant director Anne M. Mulcahy.

172. Plaintiff has not made a demand on the present Board to institute this action because such a demand would have been a futile, wasteful and useless act.

173. Any suit by the current directors of J&J to remedy the wrongs complained of herein would expose the defendants themselves and their friends and business allies to significant personal liability for their breaches of fiduciary duties and other misconduct. Each officer and director of J&J owed J&J and/or its shareholders the duty to exercise a high degree of loyalty, good faith, independence, care and candor in the management and administration of the affairs of the Company. The Current Director and Former Director Defendants have demonstrated their

unwillingness and/or inability to act in compliance with their fiduciary obligations and/or to sue themselves and/or their fellow directors for the wrongful conduct described herein. Each of these defendants is accused of wrongdoing and recommending, approving and signing Company filings, and thus faces a substantial likelihood of liability thereby rendering any demand upon them futile.

174. According to the Compensation & Benefit Committee's Charter, it is responsible for approval of Executive Committee Members' compensation, including defendant Weldon. In 2009, Weldon received over $1.8 million in base salary from J&J. The Compensation Committee is comprised of defendants Johns, Perez and Prince. As the members of the Compensation Committee singularly control approval of Weldon's compensation, Weldon will not institute this action against defendants Johns, Perez and Prince. To do so would jeopardize his own compensation. Thus, demand on Weldon is futile.

175. Additionally, defendant Weldon has been an employee of the Company since 1971 and on the Board since 2001. Weldon has been CEO since 2002, pursuant to which he has received and continues to receive substantial monetary compensation and other benefits. Upon joining the Company in 1971, Weldon was a sales representative at McNeil Pharmaceutical. In 1989, he became Vice President, Sales and Marketing for Janssen Pharmaceutical. He was J&J Company Group Chairman when the FDA sent its January 5, 1999 violation letter to J&J's Janssen Research Foundation, which specifically admonished J&J that its off-label promotions were

improper. Thus, Weldon is well versed on the applicable laws and regulations distinguishing between lawful rebates and illegal kickbacks. It was on his watch that J&J engaged in the long-running illegal scheme with Omnicare detailed herein. Further, Weldon is dependent on the conflicted directors referenced herein for his substantial remuneration. Thus, a reasonable doubt is raised that defendant Weldon is disinterested and independent, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action.

176. The Individual Defendants were aware of and participated in and approved the wrongs alleged herein. Thus, they have knowingly chosen not to exercise the fiduciary duties of loyalty, good faith, independence, and candor owed to the Company, and to protect J&J or to rectify the illegal practices complained of herein. They therefore have approved of and continue to participate in a course of corporate misconduct that includes the following:

(a) Approving and/or condoning the illegal conduct and practices described herein. Each Individual Defendant had the ability and/or opportunity to prevent these practices. The Board is responsible for overseeing the Company's compliance with legal requirements and, therefore, all directors are liable for not ensuring that the officers and employees of the Company did not expose the Company to unnecessary risk. Because the Individual Defendants are liable for approving and directing the illegal conduct described herein, demand would be futile.

(b) Current Director Defendants Coleman, Cullen, and Mullin serve on the Audit Committee. Members of the Audit Committee, because of their position of control and authority over J&J, were able to, and did, directly and indirectly, control the wrongful acts complained of herein. The members of the Audit Committee failed to ensure that the Company had and maintained adequate internal financial controls and failed to ensure the integrity of the Company's financial statements. Because members of the Audit Committee had an affirmative duty to ensure that the Company maintained adequate internal controls over financial reporting and the integrity of the Company's financial statements and failed to do so, members of the Audit Committee breached their fiduciary obligations due the Company. Accordingly, the Current Director Defendants on the Audit Committee could not impartially respond to a demand and it would have been futile.

(c) The wrongful conduct complained of herein by the Individual Defendants amounted to breaches of their fiduciary duties of good faith, independence, loyalty and candor to J&J and its shareholders.

(d) The Individual Defendants, in particular the current and former members of the Audit Committee, refused to put into place adequate internal controls and adequate means of supervision to stop the wrongful conduct alleged herein despite the fact that the Board knew and/or recklessly ignored such wrongful business practices. These acts, and the acts alleged in this action, demonstrate a pattern of gross misconduct, which conduct is not taken honestly and in good faith.

(e) Moreover, despite the Individual Defendants having had knowledge of the claims and causes of action raised by plaintiff, the current Board has failed and refused to seek to recover for J&J for any of the wrongdoing alleged by plaintiff herein.

177. A majority of the current Board – defendants Coleman, Cullen, Lindquist, Mullin, Satcher, and Weldon – were also directors during the time (1999-2004) the Omnicare illegal kickback scheme occurred. These Board members approved of the illegal kickback scheme or tacitly approved it by looking the other way during the widespread and far reaching scheme. Therefore, a majority of the members of the current Board are not disinterested with respect to the allegations in this Complaint. The approval of actions by the Company that violate applicable law can never be protected by the business judgment rule. Nor can such malfeasance ever constitute the "good faith" required of corporate fiduciaries.

178. Further, this action does not arise from a single incident, but numerous different schemes, some of which lasted at least 5 years, which involved hundreds of millions of dollars, and were common knowledge throughout the Company. Serious violations of applicable law occurred systematically and at every level of the Company as a direct result of the Board's decision to embrace a policy of calculated legal violations as the Company's deliberate business strategy. There is no legitimate "business judgment" involved in devising or carrying out such an unlawful policy. Accordingly, demand on the Board is excused.

179. Defendants Coleman, Cullen, Lindquist, Mullin, Satcher, and Weldon are incapable of impartially considering a demand because they face a substantial likelihood of liability for their role in the illegal Omnicare kickback scheme. Pursuant to New Jersey law and the Company's own Principles of Corporate Governance, these Board members were required to stay actively involved in the management of the Company and act to prevent J&J from violating applicable laws and regulations. Each of these directors, however, knowingly chose not to act to stop and prevent further violations of federal laws and regulations in the face of numerous and overwhelming facts alerting them to what was occurring at the Company, including the breadth of and length of time that the wrongdoing occurred, the amount of money being exchanged pursuant to the scheme, and that the scheme was prevalent at J&J.

180. In addition, defendants Coleman, Cullen, Lindquist, Mullin, Satcher, and Weldon also occupied positions at the Company and on Board committees that charged them with even greater responsibility for oversight of the Company. Coleman has served on the Audit Committee since 2003. Cullen has served on the Audit Committee since 1998 (and chaired that committee since 2000) and the Nominating & Corporate Governance Committee since 2004. Mullin served on the Nominating & Corporate Governance committee from 2000 to 2005 and the Audit Committee since 2000. Satcher has served on the Public Policy Advisory Committee since 2003. Lindquist has served on the Public Policy Advisory Committee since

2004. The additional responsibilities of the members of these committees are described above.

181. All of the Individual Defendants signed the Company's disclosures, including the Annual Reports on Form 10-K, many of which described the investigations by the various U.S. Attorneys, states' attorneys general, and federal regulators into the conduct alleged herein. Due to the Individual Defendants' responsibilities to J&J and the widespread violation of applicable law at the Company, to the extent that any of them did not have actual knowledge of the violations, such lack of knowledge could only be the product of willful blindness that constitutes a bad faith breach of their duties.

182. Specifically, and as set forth herein, every Company Form 10-K filing since 2003 has disclosed the investigation by the U.S. Attorney's Office for the District of Massachusetts into off-label marketing of Topamax. The 2009 Form 10-K noted that current and former employees have testified before the grand jury, and discussions were under way to resolve the matter.

183. Every Company Form 10-K since 2004 has disclosed and discussed the January 20, 2004 subpoena served on the Company's Janssen unit from the Office of the Inspector General of the United States Office of Personal Management regarding marketing of Risperdal®. The 2005 Form 10-K disclosed that the U.S. Attorney's Office for the Eastern District of Pennsylvania also served a subpoena on the Company regarding Risperdal®.

184. Every Company Form 10-K since 2005 has disclosed and discussed the September 2005 subpoena J&J received from the U.S. Attorney's Office for the District of Massachusetts seeking information regarding J&J's sales and marketing of eight drugs, including Risperdal®, to Omnicare. Numerous employees were subpoenaed to testify in connection with that investigation.

185. Every Company Form 10-K since 2007 has disclosed and discussed the coordinated investigations by U.S. Attorney's Offices in San Francisco, Philadelphia and Boston into J&J's corporate supervision and oversight of three different subsidiaries with respect to the sales and marketing of three different drugs: Risperdal®, Topamax, and Natrecor. Defendants Weldon, Coleman, Cullen, Johns, Longbo, Lindquist, Mullin, Perez, Prince, and Satcher each signed these filings

186. Moreover, these defendants were required to act upon this information to protect the Company from continued legal violations being committed in its name. Rather than doing so, these defendants, in violation of their legal obligations, consciously ignored the information presented to them concerning the Company's extensive legal violations. As a result, defendants Coleman, Cullen, Lindquist, Mullin, Satcher, and Weldon face a substantial likelihood of liability for their conduct and demand is, therefore, excused.

187. Defendants Coleman, Cullen, Lindquist, Mullin, Satcher, and Weldon bear a substantial likelihood of liability arising from their violation of the federal securities laws in connection with their issuance of the Proxy Statements. The Proxy

Statements constituted solicitations by these defendants, as applicable, for which they may be held personally liable under the federal securities laws. As set forth above, the Proxy Statements were materially inaccurate and incomplete which caused significant harm to the Company. As a result, these defendants each bear a substantial likelihood of liability for their violations of the federal securities laws, are conflicted and not disinterested with respect to such claims, and are fundamentally disabled from impartially considering a demand to impose liability on themselves for violating their own statutory disclosure obligations.

188. Moreover, the acts complained of constitute violations of the fiduciary duties owed by J&J's officers and directors and these acts are incapable of ratification.

189. Despite having knowledge of the claims and causes of action raised by plaintiff, the current Board has failed and refused to seek to recover on behalf of J&J for any of the wrongdoing alleged by plaintiff herein.

190. Any suit by the current directors of J&J to remedy these wrongs would likely expose the Individual Defendants and J&J to further violations of federal laws that would result in civil actions being filed against one or more of the Individual Defendants. Thus, they are hopelessly conflicted from making an independent determination whether to sue themselves.

191. J&J has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Individual Defendants and current Board have not filed any lawsuits against themselves or others who were responsible

for that wrongful conduct to attempt to recover for J&J any part of the damages J&J has suffered and will continue to suffer thereby.

192. Plaintiff has not made any demand on the other shareholders of J&J to institute this action since such demand would be a futile and useless act for at least the following reasons:

(a) J&J is a publicly held company with over 2.7 billion shares outstanding and thousands of shareholders;

(b) making demand on such a number of shareholders would be impossible for plaintiff who has no way of finding out the names, addresses, or phone numbers of shareholders; and

(c) making demand on all shareholders would force plaintiff to incur excessive expenses, assuming all shareholders could be individually identified.

COUNT I

Against Defendants Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, Satcher, and Weldon (the "Proxy Defendants") for Violations of Section 14(a) of the Exchange Act and Rule 14a-9 Promulgated Thereunder Based upon Material Misstatements in and Omissions from J&J's 2008, 2009 and 2010 Proxy Statements

193. Plaintiff incorporates by reference ¶¶1-192 above.

194. The Proxy Defendants caused J&J to issue the 2008, 2009 and 2010 Proxy Statements to solicit shareholder votes for the election of directors.

195. As alleged in detail above, these Proxy Statements contained materially inaccurate and incomplete disclosures.

196. The inaccuracies and omissions in each Proxy Statement concerned matters of material importance to the Company and were material to shareholders in response to the solicitations embodied in each Proxy Statement. The Proxy Statements were an essential link in defendants' conscious disregard for the illegal kickback scheme and off-label marketing schemes and rebate practices, as disclosure to the shareholders of the truth would have brought an end to J&J's shareholders' endorsement of the Proxy Defendants as fiduciaries.

197. The Proxy Defendants' failure to include these material facts in the 2008, 2009 and 2010 Proxy Statements rendered the Proxy Statements materially inaccurate and incomplete, in violation of §14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder.

198. As a direct and proximate result of the issuance of materially inaccurate and incomplete Proxy Statements, J&J suffered direct and significant damages in the form of, *inter alia*, the perpetuation of the widespread misconduct committed in the Company's name and substantial additional liabilities related to numerous *qui tam* "whistleblower suits," consumer class actions, and other lawsuits and investigations, as well as significant expenses related thereto.

199. In connection with the improper acts alleged under this Count, the Proxy Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications, or the facilities of a national securities exchange.

200. This count is only alleged against the Proxy Defendants as to those proxies that were issued during their terms as directors on the Board.

201. Plaintiff, on behalf of J&J, thereby seeks relief for damages inflicted upon the Company as a result of the misleading and incomplete proxy materials.

COUNT II

Against Defendants Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince and Satcher (the "Section 29(b) Defendants") for Violation of Section 29(b) of the Exchange Act

202. Plaintiff incorporates by reference ¶¶1-192 above.

203. The Company paid fees, stock awards and other compensation to the Section 29(b) Defendants as a result of these defendants' violation of the Exchange Act and rules prescribed thereunder, including Rule 14a-9. These defendants obtained their positions as directors and the fees, awards, and other compensation paid to directors pursuant to their materially false statements, omissions, and/or schemes or practices that damaged J&J. There is contractual privity between J&J and the Section 29(b) Defendants. J&J and its shareholders are in the class of persons the Exchange Act and rules promulgated thereunder was designed to protect.

204. Accordingly, the Section 29(b) Defendants' entire fees, awards and other compensation must be rescinded.

COUNT III

Against the Individual Defendants for Breach of Fiduciary Duty

205. Plaintiff incorporates by reference ¶¶1-192 above.

206. As alleged in detail herein, the Individual Defendants, by reason of their positions as officers and directors of J&J owed J&J fiduciary obligations of loyalty, good faith, independence and candor in the management and administration of the affairs of the Company and were and are required to use their utmost ability to manage J&J in a fair, just, honest, and equitable manner.

207. The Individual Defendants violated their fiduciary duties of loyalty, good faith, independence and candor by failing in their enumerated duties which caused the violations of federal and state law that led to the *qui tam* actions, the DOJ's intervention in the *qui tam* actions, and the class action.

208. But for the abdication of the Individual Defendants' fiduciary duties, the Company would not have been damaged. Accordingly, all of the Individual Defendants breached their fiduciary duties.

209. As a direct and proximate result of the Individual Defendants' foregoing breaches of fiduciary duties, the Company has suffered significant damages, as alleged herein.

210. Plaintiff, on behalf of J&J, has no adequate remedy at law.

COUNT IV

Against All Defendants for Abuse of Control

211. Plaintiff incorporates by reference ¶¶1-192 above.

212. Defendants' misconduct alleged herein constitutes a breach of their fiduciary duties because they abused their ability to control and influence J&J, for which they are legally responsible.

213. As a direct and proximate result of defendants' abuse of control, J&J has sustained significant damages.

214. As a result of the misconduct alleged herein, the defendants are liable to the Company.

COUNT V

Against All Defendants for Gross Mismanagement

215. Plaintiff incorporates by reference ¶¶1-192 above.

216. By their actions alleged herein, the defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of J&J in a manner consistent with the operations of a publicly held corporation.

217. As a direct and proximate result of the defendants' gross mismanagement and breaches of duty alleged herein, J&J has sustained significant damages.

218. As a result of the misconduct and breaches of duty alleged herein, the defendants are liable to the Company.

COUNT VI

Against All Defendants for Waste of Corporate Assets

219. Plaintiff incorporates by reference ¶¶1-192 above.

220. As a result of the improper conduct described herein, and by failing to properly consider the interests of the Company and its public shareholders and by refusing to conduct proper supervision, the defendants have caused J&J to waste valuable corporate assets and incur to defend defendants' unlawful actions.

221. As a result of the waste of corporate assets, the defendants are liable to the Company.

COUNT VII

Against Defendants Weldon, Larsen, Darretta and Lenehan (the "Officer Defendants") for Unjust Enrichment

222. Plaintiff incorporates by reference ¶¶1-192 above.

223. By their wrongful acts and omissions, the Officer Defendants were unjustly enriched at the expense of and to the detriment of J&J. In particular, the Officer Defendants were unjustly enriched through bonuses and other incentive compensation that they achieved from increased sales of J&J's drugs as a result of the illegal kickbacks. On information and belief, but for the illegal rebate scheme, the Officer Defendants would not have achieved their annual incentive compensation goals. Accordingly, because the Officer Defendants' meeting of their compensation goals was the result of the illegal promotion of J&J's drugs through the kickback and rebate scheme rather than sustainable growth of J&J's business, the Officer Defendants were unjustly enriched by the bonuses and other incentive compensation that they received.

224. Plaintiff, as a shareholder and representative of J&J, seeks restitution from the Officer Defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by the Officer Defendants, and each of them, from their wrongful conduct and fiduciary breaches.

PRAYER FOR RELIEF

WHEREFORE, plaintiff demands judgment as follows:

A. Against all of the Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' violation of federal law, breaches of fiduciary duties and unjust enrichment;

B. Directing J&J to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect J&J and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote the following Corporate Governance Policies:

(i) a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;

(ii) a provision to permit the shareholders of J&J to nominate at least three candidates for election to the Board;

(iii) a proposal to ensure the accuracy of the qualifications of J&J's directors, executives and other employees; and

(iv) a proposal to appropriately test and then strengthen the internal control functions.

C. Extraordinary equitable and/or injunctive relief as permitted by law, equity and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on or otherwise restricting Individual Defendants' assets so as to assure that plaintiff on behalf of J&J has an effective remedy;

D. Awarding to J&J restitution from the Individual Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the Individual Defendants;

E. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: May 14, 2010

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